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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/518,679	08/16/2005	Richard Bell	PG4798USW	2845

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EXAMINER

ROBINSON, BINTA M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/518,679

Applicant(s)

BELL ET AL.

Examiner

Binta M. Robinson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15, 17, 20 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9, 10 and 17 is/are rejected.
- 7) ☒ Claim(s) 7, 8, 11- 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. <u>12/20/05</u> . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12/17/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Claims 1-15, 17, 20 and 21 are pending. As the applicant noted in a telephone conversation on 12/20/05, the claims stated to be pending in the remarks dated 12/17/04 are inconsistent with the claims actually depicted as pending in the preliminary amendment and the claims filed 12/17/04.

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

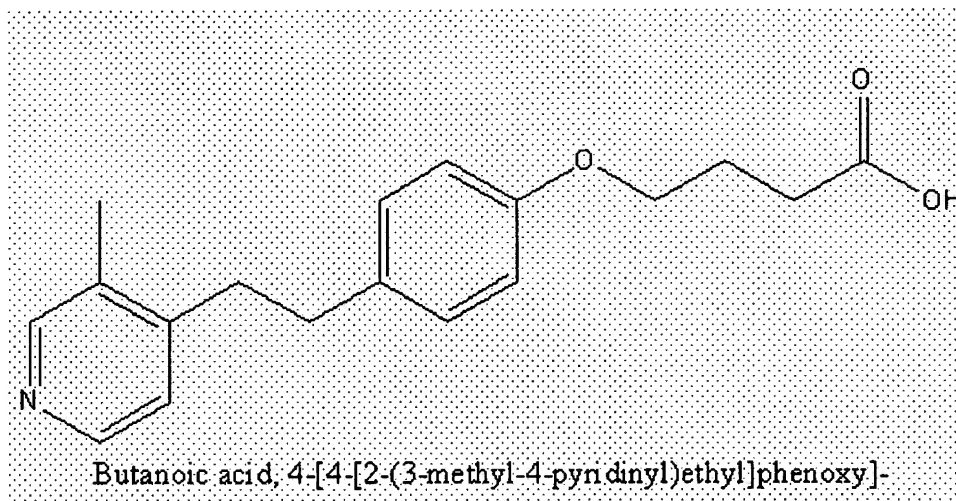
Group I, claim(s) 1-15, 17, drawn to the compounds and pharmaceutical composition.

Group II, claim(s) 20-21, drawn to the method of treating various diseases with the compound.

The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I and II are linked by the technical feature of compounds in group I. However, as evidenced by Chiellini et al, (See compound, GC-1) these compounds do not make a contribution over the prior art and do not link the product and method claims into a single general inventive concept. Additionally, alternative members of the Markush group of compounds in Groups I and II do not have a common core, or a common utility and

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therefore unity is lacking. (See MPEP 1850, Section III, part B). For example, the



compound,

Is used as an allergy inhibitor (See US 5399575), whereas the compound, GC-1 is a thyroid hormone receptor inhibitor.

If applicants elect the product and if it is found free of the prior art, the method claims may be eligible for rejoinder practice under 821.04(b).

Applicant is required, in reply to this action, to elect a single species within the elected group. The reply must also identify the claims readable on the elected species, including any claims subsequently added. For example, species as identified at pages 4-10 and in examples 25-144 at pages 90-140.

During a telephone conversation with Robert Brink on 12/19/05 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-15, 17; example 64 on page 107 of the specification was elected as a species. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-21

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are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chiellini et. al. (Bioorganic & Medicinal Chemistry). Chiellini et. al. teaches the compounds, GC-1 and GC-13. At page 334, see the compounds.

The difference between the prior art compound and the instantly claimed compounds is the alkylene group between the two phenyl radicals. In the instant compounds, the alkylene group is an ethylene. In the prior art compound, the alkylene group is a methylene. The prior art compound and the instant compounds are homologues of each other. Homologues are compounds that differ by a methylene linkage.

It would have been obvious to one of ordinary skill in the art to synthesize homologues of this class of compounds. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-5, 10, 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Friebe et. al. (See Reference A).

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Friebe et. al. teaches the compound as shown in Formula I, where A is alkylene with 1 to 2 carbon atoms, B is an oxygen atom, m is 1, X is a valency bond, Y is a valency bond, Z is halogen, C1-to C6 alkyl, R is COOH. At the abstract, see the compound of formula I and the radicals defined. The difference between the prior art compound and the instantly claimed compounds is the teaching of a genus that overlaps in subject matter with the instant genus. The patentee teaches a very limited number of selections for the variables of this genus that are small enough in number to be combined to form the instant genus. Since the patentee teaches a small group of compounds within a genus that overlaps in subject matter with the instant genus, it would have been obvious for one of ordinary skill in the art to easily envision and test the compounds that overlap with the prior art genus of compounds. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

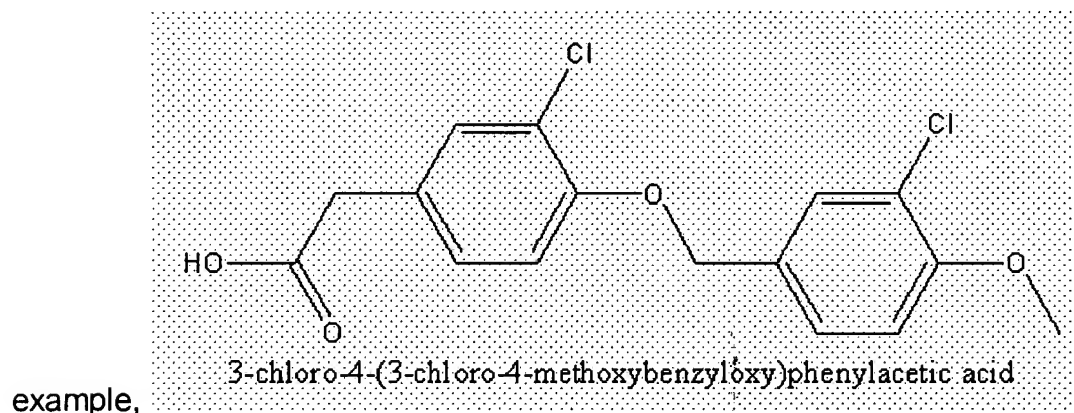
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 9, 10, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grimova et. al.

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Grimova teaches a class of anti-inflammatory substituted phenylacetic acids, for



The difference between the prior art compound and the instantly claimed compound is the alkylene group between the carboxyl group and the phenyl. In the instant compound, the alkylene group is an ethylene group. In the prior art compound, the alkylene group is a methylene group. The prior art compound and the instant compound are homologues of each other. Homologues are compounds that differ by a methylene linkage.

It would have been obvious to one of ordinary skill in the art to synthesize homologues of this class of compounds. Accordingly, the compounds are deemed unpatentable therefrom in the absence of a showing of unexpected results for the claimed compounds over those of the generic prior art compounds.

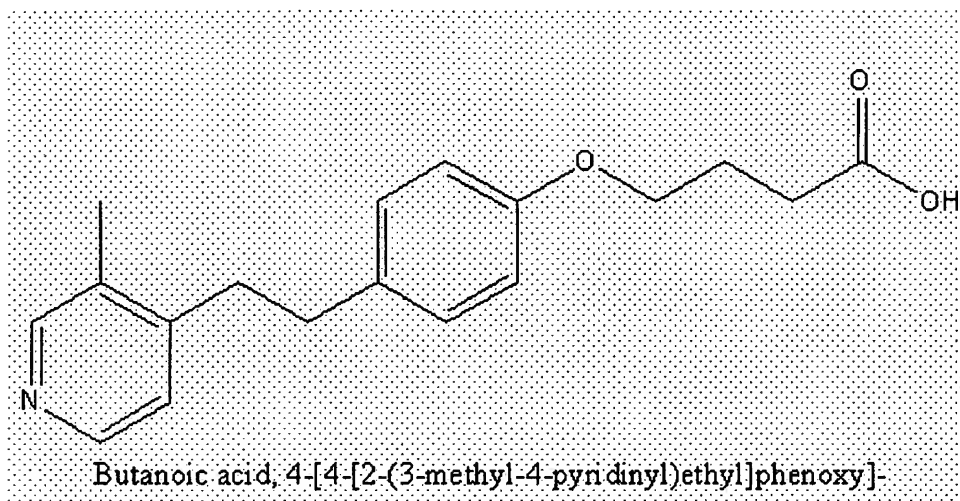
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 10, 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Hcaplus 117:131082. (See Reference U).

Hcaplus 117:131082 discloses the instant compound,



The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 17 is indefinite because there is no reference to a pharmaceutically acceptable, inert carrier.

The IDS filed 12/17/04 has been considered. The references that have been lined through will not be considered until provided to the examiner.

The elected species is allowable.

Claims 7-8, 11-15 are objected to because they are based on a rejected claim.

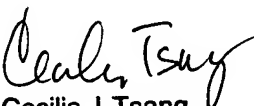
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703)305-3592, and (703)305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)-272-1600.

BMR
December 27, 2005


Cecilia J. Tsang
Supervisory Patent Examiner
Technology Center 1600